

REMARKS

Claims 1-28 and 31-40 are pending in the application and are not further amended herein. Claims 29 and 30 had been cancelled without prejudice or disclaimer in Applicant's response to the Office Action dated March 23, 2006.

In the Office Action dated October 11, 2006, the Examiner withdrew the previous allowance of claims 1-16, 19-28, 31-33 and 37-40, in view of newly discovered Douglas patent (U.S. Patent No. 6,923,791). As discussed in further detail below, the Douglas patent is not prior art with respect to the subject matter claimed in the present application (and the subject matter that the Examiner relied upon in the Douglas patent to form the new rejection).

In the Office Action dated October 11, 2006, claims 1-28 and 31-40 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,923,791 to Douglas (Douglas patent). The rejection of claims 1-28 and 31-40 is respectfully traversed, in view of the following remarks.

More specifically, the Douglas patent is not prior art to the present application, with respect to the subject matter recited in the presently pending claims. The Douglas patent was filed on March 30, 2004 (which is after the November 10, 2003 filing date of the present application). While the Douglas patent claims priority on a provisional patent application filed on March 31, 2003, that provisional patent application fails to disclose or suggest the subject matter recited in the present claims.

For example, the Douglas provisional patent application fails to disclose or suggest a connector that is rotatable on a base by more than 5 degrees and less than 360 degrees. Rotation features in the Douglas patent that the Examiner references were not included in the provisional patent application but, instead, were added later, for the March 30, 2004 filing of the Douglas patent (and, thus, would have an effective filing date of March 30, 2004). Therefore, the Douglas patent's filing date (March 30, 2004) for those rotation features is later than the November 10, 2003, filing date of the presently pending application. Hence, with regard to the subject matter of

the presently pending claims and the portions of the Douglas patent relied upon by the Examiner, the Douglas patent is not prior art under 102(e) and could not have anticipated the presently pending application.

Claims by Applicant

The claims under the new ground of rejection (claims 1-28 and 31-40) include independent claims 1, 10, 15, 24, 31 and 34. Each of those independent claims (and, thus, each of the dependent claims, dependent thereon) recite features that are neither disclosed nor suggested in the provisional patent application that underlies the Douglas patent.

Claim 1 of the present application recites an infusion set that includes (among other features) a connector that is rotatable on the base, to more than 5 degrees and less than 360 degrees. Similarly, claim 10 recites a method for using an infusion set that includes (among other features) a connector on a base, where the connector comprises a delivery tubing and at least one stop for inhibiting rotation of the connector beyond 360 degrees with respect to the base, wherein the delivery tubing is allowed to move more than 5 degrees and less than 360 degrees.

Additionally, Claim 15 of the present application recites an infusion set that includes (among other features) a connector that moves more than 5 degrees and is restricted by the base to less than 360 degrees, wherein the connector comprises at least one stop for inhibiting rotation of the connector beyond 360 degrees, and wherein a fluid passes from the tubing to the cannula when the connector is attached to the base. Similarly, Claim 24 recites an infusion set that includes (among other features) at least one stop for inhibiting rotation of the connector beyond 360 degrees with respect to the base, wherein adjusting the position of the delivery tubing is allowed to be more than 5 degrees and less than 360 degrees around the axis that is substantially perpendicular to said first surface of said base.

Also, Claim 31 of the present application recites an infusion set that includes (among other features) a connector removably attachable to the base in any one of at least two different

connection positions, wherein said connector being rotatable on said base, each connection position of said at least two different connection positions allowing for different possible relative orientations of said connector with respect to said base when said connector is rotated on said base and a stop for preventing further rotation of said connector in a particular rotational direction on said base when said stop contacts one of said at least two barriers of said base; and wherein a plurality of intervals around said circumference of said base are defined between barriers of said at least two barriers. Similar features are recited in claim 34.

An infusion set having features as recited in the above-cited independent claims was neither described nor suggested in the provisional patent application from which the Douglas patent claims priority. Accordingly, the provisional patent application neither anticipates or suggests the invention recited in any of the claims pending in the present application.

Office Action Rejection Based on the Douglas Patent

In the Office Action dated October 11, 2006, the portion of the Douglas patent at Col. 4 line 14 through 24 was cited as describing rotational and the rotation inhibiting features. The Office Action refers to the Douglas patent as disclosing an infusion set comprising a base (100 disclosed in Col 3 line 1 through Col 5 line 38, Fig. 1 and 2), for providing infusion path, the base having a first surface that faces a skin surface of a user when the base is supported on the skin surface and when the infusion set is used to pass fluids to the user, a cannula (110 disclosed in Fig. 1, 2, col. 3 line 28 and 4 line 55) connected to and extending away from the base, a connector (200 disclosed in Fig. 1, 2 and Col. 3 line 19 to Col. 4 line 24) removably attached to the base, and tubing (215 disclosed in Fig. 9 and Col. 4 line 61 - 64) affixed to the connector, wherein the connector is rotatable on the base to more than 5 degrees and less than 360 degrees around the axis that is substantially perpendicular to the first surface of the base, when the connector is attached to the base, wherein the connector comprises at least one stop (231 disclosed in Fig 1, 2 and Col 4 line 6, 14-25) for inhibiting rotation of the connector beyond 360 degrees, wherein the base comprises at least one barrier (see col. 4, lines 14-24), wherein the stop extends away from the surface of the connector, and the barrier is arranged to restrict the

movement of the stop when the connector is rotated around the base and wherein the connector can be limited to any degree between 5 and 360, and further comprising a hub and needle removably attached to the base and a cover for the needle.

As described below, much of the above-cited subject matter from the Douglas patent was not included in the provisional patent application that formed the basis for the claim of priority in the Douglas patent. A copy of the provisional patent application is attached hereto as an exhibit. A comparison of the Douglas patent with the Douglas provisional patent application clearly shows that the Douglas provisional patent application fails to disclose or suggest much of the subject matter described in the later-filed Douglas patent. For example, the provisional patent application fails to disclose or suggest a connector that is rotatable on the base to more than 5 degrees and less than 360 degrees.

Disclosure of the Douglas Provisional Application Compared to the Douglas Patent

In the "Summary of the Invention" section of the Douglas patent on Col. 2 in lines 26 to 36 states:

... the connecting hub can be rotatable with respect to the housing. This gives the patient greater comfort and flexibility since an infusion tube extending from the connecting hub can be rotated to different radial positions, as desired. As will be explained, the present connecting hub can be rotatable with respect to the housing through a full 360 degrees, some through amount less than 360 degrees, or alternatively, not be rotatable at all.

However, the above cited portions of the Douglas patent were not present in the corresponding provisional patent application. While the provisional application has a "Brief Summary of the Present Invention" section, that section includes no corresponding text as quoted above. When the connector is mentioned or represented in the provisional application (Pg. 1, 4, 6 and Fig. 1), the features or quality described is "quick-release" (not rotatable).

Next in the "Detailed Description of the Drawings" section, the Douglas patent in Col. 4. lines 1 to 13 states:

A further advantage of the design shown in FIG. 2 is that connecting hub 200 may be freely rotatable with respect to housing 100 even after connecting hub 200 has been attached to housing 100. This is because infusion needle 210 is preferably positioned in the center of device 10 (i.e.: co-linear with axis 300) and because tabs 231 may be freely moveable along through notch 135 (which runs around housing 100 between upper and lower portions 130 and 140 respectively). As a result, connecting hub 200 may freely rotate to different radial positions with respect to housing 100 since connecting hub 200 simply rotates around centrally-located infusion needle 210 while tabs 231 slide around within notch 135 around the perimeter of housing 100.

However, the Douglas provisional patent application does not include the above quoted text and does not have a corresponding Fig. 2 that is included in the Douglas patent. While the provisional application has a "Detailed Description of the Drawings" section, that section includes no corresponding text as quoted above. The Douglas provisional patent application discloses a connecting hub 200 (as a "quick-release" connector assembly 40 on Pg. 6 and Fig. 1) and a housing 100 (as the injection port assembly 10 on Pg. 6, Fig. 1 and 2). However, the Douglas provisional patent application does not disclose or suggest rotation, sliding or movement of any type. Additionally, the Douglas provisional patent application does not disclose or suggest a "notch" or "tabs" that inhibit rotation beyond 360 degrees.

Next in the "Detailed Description of the Drawings" section, the Douglas patent in Col. 4 line 14 to 25 states:

In optional embodiments, stops (not shown) may be positioned around notch 135 to limit rotation of connecting hub 200 with respect to housing 100. As a result, the present invention is understood to encompass embodiments wherein connecting hub 200 is fully rotatable 360 degrees with respect to housing 100, or rotatable less than 360 degrees with respect to housing 100, or wherein connecting hub 200 is not rotatable with respect to housing 100 at all. Consequently, the present invention encompasses embodiments wherein connecting hub 200 is attachable to housing 100 at different rotational positions.

However, the Douglas provisional patent application does not include the above-quoted text and, as stated above, does not disclose or suggest a notch 135, a stop or full rotation of 360 degrees with respect to any of the features of the device. While the provisional application has a "Detailed Description of the Drawings" section, that section includes no corresponding text as quoted above. The words rotation, rotational or movement does not appear in the Douglas provisional patent application whereas they were added to the later-filed Douglas patent.

The provisional patent application does not include corresponding Figs. 2 – 12 from the later-filed Douglas patent. Lastly, the provisional patent application does not contain most of the description corresponding to Col. 3, 4 and 5 which is all of the detailed description of the Douglas patent.

Conclusion

The Douglas patent (U.S. Patent No. 6,923,791) has a filing date of March 30, 2004, which is after the filing date of the present application and, thus, the Douglas patent, itself, is not prior art to the present application.

While the Douglas patent claims a priority filing date of a provisional patent application (60/459,252), the Douglas provisional patent application does not disclose or suggest the rotatable or the rotation inhibition features. Accordingly, the provisional patent application does not disclose or suggest the presently claimed invention. In that regard, the Douglas patent is not "prior art" to the present application with respect to the subject matter of the presently claimed invention.

Instead, with respect to features that were cited by the examiner, the Douglas patent has an effective filing date of March 30, 2004 that is after the applicant's filing date (November 10, 2003). Since the Douglas patent has a later filing date than the presently pending application, the Douglas patent is not prior art under 35 U.S.C. §102(e). Therefore, the Douglas patent could not anticipate the presently pending application.

Applicant believes that in consideration of the above argument, the present application is now in condition for allowance. Favorable reconsideration of the application is respectfully requested.

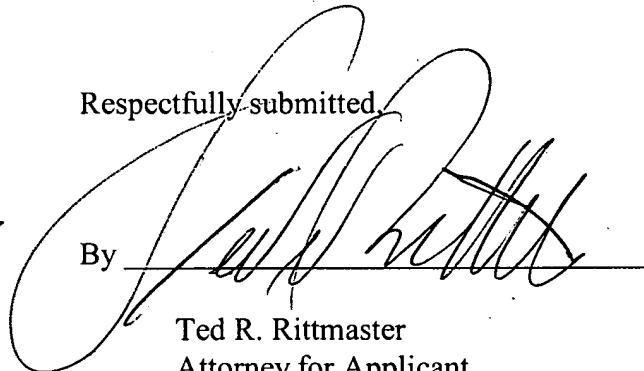
The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

Date

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By



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